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Maraviroc

pronounced as (mah rav' er rock)

IMPORTANT WARNING:

Maraviroc may cause damage to your liver. You may experience an allergic reaction to maraviroc before you develop liver damage. Tell your doctor if you have or have ever had hepatitis or other liver disease. If you experience any of the following symptoms, stop taking maraviroc and call your doctor immediately: itchy rash; yellowing of the skin or eyes; dark-colored (tea-colored) urine; vomiting; or upper right stomach pain.

Maraviroc may cause a severe allergic reaction, which may be life-threatening. If you experience a rash along with any of the following symptoms, stop taking maraviroc and call your doctor right away: nausea; fever; flu-like symptoms; muscle or joint pain; blisters or sores in the mouth; swollen, red, peeling, or blistering skin; redness or swelling of the eyes; swelling of the mouth, face, or lips; difficulty breathing; pain, aching, or tenderness on the right side below the ribs; or loss of appetite.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests to check your body's response to maraviroc.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with maraviroc and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) to obtain the Medication Guide.

Talk to your doctor about the risks of taking maraviroc.

Why is this medication prescribed?

Maraviroc is used along with other medications to treat a certain type of human immunodeficiency virus (HIV) infection in adults and children who weigh at least 4.4 lb (2 kg). Maraviroc is in a class of medications called HIV entry and fusion inhibitors. It works by decreasing the amount of HIV in the blood. Although maraviroc does not cure HIV, it may decrease your chance of developing acquired

immunodeficiency syndrome (AIDS) and HIV-related illnesses such as serious infections or cancer. Taking these medications along with practicing safer sex and making other lifestyle changes may decrease the risk of transmitting (spreading) the HIV virus to other people.

How should this medicine be used?

Maraviroc comes as a tablet and a solution (liquid) to take by mouth. It is usually taken with or without food twice a day. Take maraviroc at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take maraviroc exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow maraviroc tablets whole; do not split, chew, or crush them.

Use one of the oral syringes that came with the medication for measuring the solution. Use the small (3-mL) oral syringe if your dose is 2.5 mL or less and use the large (10-mL) oral syringe if your dose is greater than 2.5 mL. Ask your doctor or pharmacist if you have any questions about how to measure your dose with the syringe. Follow the manufacturer's instructions about how to use and clean the oral syringe.

If you are giving the solution to a child, place the tip of the oral syringe into the child's mouth against the inside of the cheek. Slowly push the plunger all the way down to give all of the medication in the oral syringe. Make sure that the child has enough time to swallow the solution.

Continue to take maraviroc even if you feel well. Do not stop taking maraviroc without talking to your doctor. If you miss doses, take less than the prescribed dose, or stop taking maraviroc, your condition may become more difficult to treat. When your supply of maraviroc starts to run low, get more from your doctor or pharmacist.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking maraviroc,

- tell your doctor and pharmacist if you are allergic to maraviroc, any other medications, or any of the ingredients in maraviroc tablets or solution. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: antifungal medications such as ketoconazole (Nizoral) and itraconazole (Onmel, Sporanox); clarithromycin (Biaxin, in Prevpac); medications to treat HIV or AIDS; medications to treat high blood pressure; idelalisib (Zydelig); certain medications to treat seizures such as carbamazepine (Carbatrol, Epitol, Tegretol), phenobarbital (Luminal), and phenytoin (Dilantin, Phenytek); nefazodone; ribociclib (Kisqali); rifabutin (Mycobutin); rifampin (Rifadin, Rimactane, Rifamate, others); and telithromycin (no longer available in U.S.; Ketek). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor what herbal products you are taking, especially St. John's wort. You should not take St. John's wort during your treatment with maraviroc.
- tell your doctor if you have or have ever had low blood pressure, chest pain, diabetes, a heart attack, high cholesterol or fats in the blood, or heart or kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking maraviroc, call your doctor. You should not breastfeed if you are infected with HIV or if you are taking maraviroc.
- you should know that your body fat may increase or move to different areas of your body, such as your breasts and upper back, while you are taking maraviroc.
- you should know that maraviroc may cause dizziness, lightheadedness, or fainting when you get up too quickly from a lying position. To help avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up. Do not drive a car or operate heavy machinery if you are dizzy while taking maraviroc.
- you should know that while you are taking medications to treat HIV infection, your immune system may get stronger and begin to fight other infections that were already in your body. This may cause you to develop symptoms of those infections. If you have new or worsening symptoms after starting treatment with maraviroc, be sure to tell your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it, and then take the next dose at the scheduled time. However, if it is less than 6 hours before your next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Maraviroc may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- cough, runny nose, or other cold symptoms
- muscle or joint pain
- pain, burning, numbness, or tingling in the hands or feet
- dizziness
- diarrhea
- constipation
- painful or difficult urination
- white sores and/or pain in the mouth or esophagus (tube between the mouth and stomach)
- difficulty falling asleep or staying asleep
- sleep walking, sleep talking, sleep terrors, or acting out in your sleep

Some side effects can be serious. If you experience any of these symptoms, or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency medical treatment:

- sore throat, fever, chills, or other signs of infection
- chest pain, pressure, or discomfort
- pain in one or both arms, back, neck, jaw, or stomach
- shortness of breath
- sweating

Maraviroc may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Discard any unused oral solution 60 days after first opening the bottle.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- dizziness, lightheadedness, or fainting when getting up too quickly from a lying position

What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Selzentry[®]

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